

## REMARKS

Claims 1 and 5-55 are pending in this application. In the non-Final Office Action mailed November 27, 2007, claims 1 and 5-55 were rejected. Claims 8, 10, 17, 20, 21, 30, 38, 41 and 54 are amended in this response. Reconsideration of the present application as amended is respectfully requested.

Support for the amendments to claims 8, 10, 17, 20, 30, 41 and 54 may be found, for example, at least in paragraphs [0040] and [0041] of the publication of Applicants' specification, and in Figures 1, 7-9 and 14-17. Claim 21 is amended to maintain consistency with claim 20, and claim 38 is amended to correct an error typographical or clerical in nature. Entry of the amendments is respectfully requested.

Claims 8-14, 17, 18, 20-42, 45-48 and 50-55 stand rejected under 35 USC 102(b) as being anticipated by EP 1 323 396 A2 to Fraser ("Fraser"). As an initial matter, Fraser was published on July 2, 2003, and the present application has a filing date of January 26, 2004. Therefore, Fraser is not prior art under 35 USC 102(b). Applicants reserve the right to remove Fraser as a reference with an affidavit under 37 CFR 1.131 in this application or in any continuing application.

Even if Fraser is citable against the present application, it does not anticipate the claims rejected thereby. It is well established that "an invention is anticipated if the same device, including all the claim limitations, is shown in a single prior art reference. Every element of the claimed invention must be literally present, arranged as in the claim." Richardson v. Suzuki Motor Co. Ltd., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The claims must not be treated as "mere catalogs of separate parts, in disregard of the part-to-part relationships set forth in the claims and that give the claims their meaning." Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Company et al., 730 F.2d 1452, 1459, 221 USPQ 481, 486 (Fed. Cir. 1984). As a result, a reference that coincidentally lists features of a claim without describing the claimed arrangement, relationship, and organization of such features cannot anticipate.

Amended independent claim 8 has been amended to clarify that, among other features, the instrument includes "a pair of opposing guide members coupled to said housing, each of said pair of guide members including a body with an outer surface and an opposite guide surface and an elongated slot opening therebetween, said slot extending along said respective guide member and said slot extending through said outer surface and said opposite guide surface of said

respective guide member, the implant being positionable between said guide surfaces". Fraser does not disclose that either of levers 12, 14 includes a slot arranged in the manner recited in claim 8. Levers 12, 14 include a recessed track 60 in the sides of levers 12, 14, but recessed track 60 does not open between or extend through the opposite outer and inner surfaces of levers 12, 14. Therefore, withdrawal of the rejection of claim 8 is respectfully requested. Therefore, claim 8 and its dependent claim are allowable at least for these reasons.

Amended independent claim 10 also recites, in combination with the other therein, "a pair of opposing guide members coupled to said housing, each of said pair of guide members including a body with an outer surface and an opposite guide surface and an elongated slot opening therebetween, said slot extending along said respective guide member and extending through said outer surface and said guide surface thereof, the implant being positionable between said guide surfaces". As discussed above, Fraser does not disclose that recessed tracks 60 of levers 12, 14 include these features. Therefore, claim 10 and its dependent claims 11-14 are allowable at least for these reasons.

Amended independent claim 17 recites, among other features, "a pair of opposing guide members coupled to said housing, each of said pair of guide members including a body with an outer surface and an opposite guide surface and an elongated slot opening therebetween, said slot extending along and extending through said outer surface and said guide surface of said respective guide member, the implant being positionable between said guide surfaces". As discussed above, Fraser does not disclose that recessed tracks 60 of levers 12, 14 include these features. Therefore, claim 17 is allowable.

Claim 18 depends from claim 17 and is allowable at least for the reasons claim 17 is and for other reasons. For example, claim 18 recites "wherein each of said slots includes an enlarged proximal end opening adapted to permit passage of said enlarged outer end of said wing therethrough." Fraser does not that recessed track 60 includes any enlarged outer end to permit passage of guide post 94 of spreader block 18 therethrough. Withdrawal of the rejection of claim 18 is respectfully requested.

Amended independent claim 20 recites, among other features, "a pair of opposing guide members coupled to said housing, each of said pair of guide members including a body with an outer surface and an opposite guide surface, the implant being positionable between said guide surfaces, wherein said guide surfaces face one another, and said guide members each include an

outer surface opposite said guide surface thereof, and said guide members each include a slot that extends through said guide surface and said outer surface thereof". As discussed above, Fraser does not disclose that recessed tracks 60 of levers 12, 14 include these features. Therefore, claim 20 is allowable.

Claims 21-29 depend from claim 20 and are allowable at least for the reasons claim 20 is allowable and for other reasons. For example, claim 28 recites "wherein said implant holder includes an elongated shaft received through a passage extending through said drive member." As discussed below with respect to claim 1, Fraser does not disclose or teach these features. Withdrawal of the rejection of claim 21-29 depending from claim 20 is respectfully requested.

Amended independent claim 30 is a method claim and recites, among other features, "providing an implant inserter comprising: a housing; a spreader positioned between the pair of guide members, the spreader including a central body and a pair of opposite wings extending therefrom slidably received in a slot formed along a central axis of a respective one of the pair of guide members wherein the guide members each include a guide surface, the guide surfaces facing one another, and the guide members each include an outer surface opposite the guide surface thereof, and the slot of each guide member extends through the guide surface and the outer surface thereof..." As discussed above, Fraser does not disclose that recessed tracks 60 of levers 12, 14 include these features. Therefore, claim 30 is allowable.

Claims 31-40 depend from claim 30 and are allowable at least for the reasons claim 30 is and for other reasons. For example, claim 31 is independently allowable for the reasons provided above with respect to claim 18, and claims 34 and 36 are independent allowable for the reasons provided below with respect to claim 1. Withdrawal of the rejection of claims 31-40 depending from claim 30 is respectfully requested.

Amended independent claim 41 recites, among other features, "a housing; a pair of opposing guide members extending distally from said housing, said pair of guide members each including an elongated body with an outer surface and an opposite inner surface facing the inner surface of the other guide member with the implant being positionable between said inner surfaces, said guide members further each including a distally extending elongated slot extending between and opening through said inner surface and said outer surface of said guide member; a central body between said pair of guide members, said central body including opposite wings extending therefrom slidably received in respective ones of said slots of said guide members..."

As discussed above, Fraser fails to disclose that recessed tracks 60 of levers 12, 14 include these features. Therefore, claim 41 is allowable.

Claims 42, 45-48 and 50-53 depend from claim 41 and are allowable at least for the reasons claim 41 is and for other reasons. For example, claim 51 is allowable for the reasons provided above with respect to claim 18. Withdrawal of the rejection of claims 42, 45-48 and 50-53 depending from claim 41 is respectfully requested.

Independent claim 54 recites, among other features, “a housing; a pair of opposing guide members extending distally from said housing, said pair of guide members each including an elongate body with an outer surface and an opposite inner surface facing the inner surface of the other guide member, said guide members further each including an elongated slot extending between and opening through said inner surface and said outer surface thereof with the implant being positionable between said guide surfaces, each of said guide members further including an abutment member adjacent a distal end thereof with said slot of said guide member extending through said abutment member, said abutment members being positionable in contact with the adjacent bony portions; a central body between said pair of guide members, said central body including opposite wings extending therefrom slidably received in respective ones of said slots of said guide members....” As discussed above, Fraser fails to disclose that levers 12, 14 include these features. Therefore, claim 54 is allowable.

Claim 55 depends from claim 54 and is also allowable. Claim 55 recites “wherein each of said slots includes a distal end between said abutment member and said distal end of said guide member along which said slot extends.” As shown in the Office Action, tracks 60 of levers 12, 14 include a distal end located at or proximally of the “abutment members”. Therefore, Fraser does not disclose claim 55 and withdrawal of the rejection of claim 55 is respectfully requested.

Claims 1, 5-7, 19, 43 and 44 stand rejected under 35 USC 103(a) as being unpatentable over Fraser in view of U.S. Patent No. 3,486,505 to Morrison (“Morrison”). The seminal case directed to application of 35 U.S.C. § 103 is *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966). From this case, four familiar factual inquiries have resulted. The first three are directed to the evaluation of prior art relative to the claims at issue, and the last is directed to evaluating evidence of secondary considerations. See, MPEP §2141. The examiner bears the burden of

establishing a prima facie case of obviousness. *See, In re Warner*, 379 F.2d 1011, 1016, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057 (1968).

To meet this burden, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Third, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *See*, MPEP § 2142, *citing In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). *KSR v. Teleflex*, 550 U.S. \_\_\_\_ (2007), makes clear that “the [Graham] factors continue to define the inquiry that controls.” *KSR* at 2. For the following reasons, these criteria have not been met and a prima facie case of obviousness has not been established.

Claim 1 recites, among other features, “said drive member includes a shaft threadingly engaged in said passage and a handle at a proximal end of said shaft; and further comprising an implant holder extending through said drive member and said spreader, said implant holder including an adjustment knob at a proximal end thereof and a distal end extending distally of said spreader.” The Office Action assert that an “implant holder 412 may extend through a drive member (see e.g., Fig. 18).” As discussed in paragraphs [0037] and [0038], Fig. 18 of Fraser illustrates a pusher rod 20b that is suitable for use with an embodiment of pusher block 18b as shown in Figs. 19A and 19B. Pusher rod 20b includes a distal tip 413, a connector segment 412 extending proximally from distal tip 413, and an annular flange 411 having a distal end 418 integral with the connecting segment 412 and a proximal end 416 mated to the rod 20. The proximal and distal ends 416, 418 may be tapered to facilitate insertion and removal of the rod 20 from pusher block 18b, and distal tip 413 can mate to a prosthesis. Rod 20b is inserted through pusher block 18b until threaded annular flange 411 engages threaded region 403 of pusher block 18b. Flange 411 is then rotated and threaded through bore 403 to position flange 411 in chamber 408, where pusher rod 20b is then free to move axially and rotate to threadingly engage distal tip 413 to the prosthesis. There is no disclosure or teaching that pusher rod 20b extends through any drive member that is receive in a passage of a housing where the drive member is “coupled to said spreader and operable to forwardly advance said spreader and the

implant positioned forwardly of said spreader toward distal ends of said guide members”.

Rather, pusher rod 20b is merely another embodiment of pusher rod 20 that is configured to pass through pusher block 18b to engage the prosthesis. Morrison fails to remedy these deficiencies of Fraser. Therefore, claim 1 is allowable for this additional reason.

Claim 5, which depends from claim 1, recites “wherein said handle of said drive member includes a proximally opening recess, and said adjustment knob of said implant holder is rotatably received in said recess.” There is no disclosure or teaching in Fraser or Morrison of that pusher rod 30 includes a handle including a proximally opening recess. Nor is there any disclosure or teaching of that pusher rod 20b with connecting segment 412 includes an adjustment knob rotatably received in such a recess of a handle of a driver member. The Office Action does not identify any teaching of these features in either of the references. Therefore, a prima facie case for rejecting claim 5 is not established.

Furthermore, claim 44, which depends from claim 43 which depends from claim 41, recites “further comprising an implant holder extending through said drive member and said central body, said implant holder including an adjustment knob at a proximal end thereof and a distal end extending distally of said central body for engagement with the implant.” As discussed above with respect to claim 1, Fraser and Morrison do not disclose or teach the claimed arrangement of the implant holder that extends through the driver member. Therefore, a prima facie case for rejecting claim 44 is not established.

In view of the above, claims 1, 5-7, 19 and 43-44 are allowable. Withdrawal of the rejection of these claims is respectfully requested.

Claims 15, 16 and 49 stand rejected under 35 USC 103(a) as being unpatentable over Fraser alone. The examiner asserts that Fraser discloses the claimed invention “except for explicitly reciting the numerous forms the connection to the housing could take. It is noted that providing ‘finger’ and a crossbar is just one way of describing an ordinary separable joint. The fingers form the opening for the crossbar or (axle or pivot pin or whatever one may wish to call it). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted a connection comprising a joint with ‘finger’ or an opening and a ‘crossbar’ or a pivot pin for the noted connection in ‘396 as doing so would involve nothing more than the substitution of an old and well-known and functionally equivalent hinge design that

could have been employed by a person of ordinary skill in the art with predictable results equally well.”

Claim 15 includes the limitation “wherein said housing comprises a coupling portion including a pair of upper fingers each defining a proximally opening receptacle and a pair of lower fingers each defining a proximally opening receptacle.” Claim 16 depends from claim 15 and recites “wherein each of said guide members includes a proximal end adapted to be positioned between a corresponding pair of said upper and lower fingers, said guide members each further including a crossbar rotatably and removably received in said receptacles defined by said corresponding pair of fingers.” Claim 49 depends from claim 41 and includes these features of claims 15 and 16. It appears that the examiner has taken the position that these features are known in the art as a matter of official notice.

Applicants respectfully traverse the position of the Office Action. There is no evidence presented that a housing with a coupling portion including a pair of upper fingers each defining a proximally opening receptacle and a pair of lower fingers each defining a proximally opening receptacle is known in the art. Nor has any evidence presented of the combination of the housing with these features and guide members that each include “a proximal end adapted to be positioned between a corresponding pair of said upper and lower fingers, said guide members each further including a crossbar rotatably and removably received in said receptacles defined by said corresponding pair of fingers” is known in the art. Applicants respectfully request the Examiner provide such evidence. As provided in MPEP §2144.03, if the Applicant challenges a factual assertion as not properly officially noticed or not properly based upon common knowledge, the examiner must support the finding with adequate evidence. As this section further states:

Any rejection based on assertions that a fact is well-known or is common knowledge in the art without documentary evidence to support the examiner's conclusion should be judiciously applied. Furthermore, as noted by the court in *Ahlert*, any facts so noticed should be of notorious character and serve only to “fill in the gaps” in an insubstantial manner which might exist in the evidentiary showing made by the examiner to support a particular ground for rejection. It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence upon which a rejection was based.

MPEP §2144.03 E (citing, *In re Ahlert*, 424 F.2d 1088, 1092, 165 USPQ 418, 421 (CCPA 1970) and *In re Zurko*, 258 F.3d 1379, 1386, 59 USPQ2d 1693, 1697 (Fed. Cir. 2001)).

Even if the official notice is taken, (a position that the Applicants traverse as stated previously), Applicants respectfully assert that one of ordinary skill in the art would have no reason to modify Fraser to arrive claims 15, 16 and 49, and that Fraser teaches away from the modification proposed in the Office Action. Fraser teaches a tool 10 with opposed levers 12, 14 each having a distal portion 12A, 14A and a proximal handle portion 12B, 14B comprising about one half the length of the respective lever 12, 14. Paragraphs [0016], [0018]. A fulcrum 16 is disposed between levers 12, 14 so that proximal handle portions 12B, 14B extend proximally from fulcrum 16, and fulcrum 16 is configured to allow the proximal handle portions 12B, 14B to be closed together and result in the opening or separation of the distal portions 12A, 14A. Paragraph [0027]. One of ordinary skill in the art would have no reason to provide fulcrum 16 of Fraser with “a coupling portion including a pair of upper fingers each defining a proximally opening receptacle and a pair of lower fingers each defining a proximally opening receptacle” since Fraser does not disclose or teach how levers 12, 14 would be engaged to such a coupling portion while retaining the proximal handle portions of levers 12, 14. Therefore, the rejection of claim 15 is traversed.

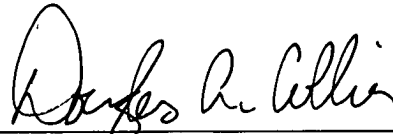
Furthermore, claims 16 and 49 recite “each of said guide members includes a proximal end adapted to be positioned between a corresponding pair of said upper and lower fingers, said guide members each further including a crossbar rotatably and removably received in said receptacles defined by said corresponding pair of fingers.” Modifying levers 12, 14 to include these features would eliminate the handle portions of the levers, and prevent the user from manipulating the levers from opening and closing the distal portions 12A, 14A as taught in Fraser. Therefore, when presented with the teachings of Fraser, one of ordinary skill in the art would be led away from modifying it in the manner suggested in the Office Action, and claims 16 and 49 are independently allowable. Applicants submit that the rejection of claim 15, 16 and 49 under 35 U.S.C. § 103(a) is improper and request that the rejection be withdrawn.



The present application is believed to be in condition for allowance. Reconsideration and allowance of the present application as amended and including claims 1 and 5-55 is respectfully requested. The Examiner is welcome to contact the undersigned to resolve any outstanding issues with respect to the present application.

Respectfully submitted:

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